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REMARKS

This is a full and timely response to the non-final Office Action mailed December 23, 2005 in the present patent application. Applicant hereby petitions for a one-month extension of time to respond and authorized payment of the requisite extension fee from the deposit account noted herein. Reconsideration of the application in light of the foregoing amendments and the following remarks is respectfully requested.

Status of Claims:

Claims 12-14 and 23-26 were withdrawn under a previous Restriction Requirement and cancelled without prejudice or disclaimer. In the present amendment, various claims are amended. New claims 27 and 28 have been added. Consequently, following entry of this amendment, claims 1-11, 13-22, 27 and 28 are pending for further action.

Prior Art:

The recent Office Action rejected claims 1-11 and 15-22 as unpatentable under 35 U.S.C. § 103(a) over the combined teachings of WO 98/37926 to Schulman et al. ("Schulman") and an article entitled "Outcome Following Implantation of a Peripheral Nerve Stimulator in Patients with Chronic Nerve Pain," by Novak et al. ("Novak"). For at least the following reasons, this rejection is respectfully traversed.

Claim 1 now recites:

A method for treating a patient with chronic pain, comprising:
providing at least one leadless stimulator having at least two electrodes;

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implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;

generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient; wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve; and

transmitting data from a transmitter of said stimulator to an external device.

(emphasis added).

In contrast, the combination of Schulman and Novak fails to teach or suggest the claimed method for treating chronic pain including transmitting data from a transmitter of a stimulator to an external device.

Consequently, the combination of Schulman and Novak does not teach or suggest all the features of claim 1. "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). Therefore, for at least this reason, the rejection of claim 1 and its dependent claims based on Schulman and Novak should be reconsidered and withdrawn.

Claim 4 has been amended herein and rewritten as an independent claim. Claim 4 now recites:

A method for treating a patient with chronic pain, comprising:
identifying a patient experiencing sensations of chronic pain;
providing at least one leadless stimulator having at least two electrodes;
implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;

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generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and

delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;

wherein the leadless stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve;

wherein the at least one peripheral nerve comprises at least one of an intercostal nerve, an intercostal nerve branch, a greater occipital nerve, a lesser occipital nerve, and a third occipital nerve.

(emphasis added).

The recent Office Action addresses claim 4 as follows. “[B]ecause Shulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation.” (Action of 12/23/05, p. 3). Applicant respectfully disagrees.

Given the unpredictable nature of biological systems and the ever-present possibility of unforeseen side affects, it is categorically incorrect to state that stimulation for a particular purpose at one specific site makes obvious stimulation at an entirely different site. Shulman does not teach or suggest a method of stimulating nerves that include any of the nerves now recited in claim 4. Novak likewise does not teach or suggest a method including stimulation of any of the nerves now recited in claim 4. Consequently, the applied prior art, taken alone or in combination, does not teach or suggest the method of claim 4.

It is incumbent upon the Office to cited prior art that actually teaches the subject matter of Applicant’s claims. M.P.E.P. § 706.02(j). In the present case, the prior art of record does not teach or suggest the method of claim 4 including the specific stimulation cites recited for the purpose of treating chronic pain.

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“To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).” M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of claim 4 should be reconsidered and withdrawn.

Claim 8 has been also amended herein and rewritten as an independent claim. Claim 8 now recites:

A method for treating a patient with chronic pain, comprising:
identifying a patient experiencing sensations of chronic pain;
providing at least one leadless stimulator having at least two electrodes;
implanting the at least one leadless stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensations of chronic pain experienced by the patient;
generating stimulation pulses within the at least one leadless stimulator in accordance with stimulation parameters; and
delivering the stimulation pulses from the electrodes of the at least one leadless stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;
wherein the chronic pain is located in one or both lower limbs, and the at least one stimulator is implanted adjacent to at least one nerve fiber of a common peroneal nerve, a common peroneal nerve branch, a sciatic nerve, a sciatic nerve branch, a saphenous nerve, a saphenous nerve branch, a posterior cutaneous nerve, a posterior cutaneous nerve branch, a sural nerve, a sural nerve branch, an obturator nerve, an obturator nerve branch, a femoral nerve, a femoral nerve branch, a lateral cutaneous nerve, and a lateral cutaneous nerve branch.

(emphasis added).

The recent Office Action fails to specifically address claim 8. However, like claim 4 above, claim 8 recites a method of treating chronic pain with an implanted stimulator stimulating at least one of a list of specific nerve sites. In contrast, neither Schulman nor Novak teach or suggest a method including stimulation of any of the listed nerves to treat chronic pain.

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As stated above, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of claim 8 should be reconsidered and withdrawn.

Independent claim 15 recites:

A method for treating a patient with chronic pain, comprising:
identifying a patient experiencing sensations of chronic peripheral pain, *wherein the chronic peripheral pain includes at least one of chronic neuropathic pain, failed back surgery syndrome, arachnoiditis, occipital neuralgia, peripheral pelvic pain, cardiac pain and back pain*;
providing at least one leadless stimulator having at least two electrodes;
providing at least one sensor;
implanting the at least one stimulator adjacent to at least one peripheral nerve of the patient, said peripheral nerve being responsible at least in part for the sensation of chronic peripheral pain experienced by the patient;
providing operating power to the at least one stimulator;
using the sensor to sense a physical condition;
determining stimulation parameters based upon the sensed condition;
generating stimulation pulses within the at least one stimulator in accordance with the stimulation parameters; and
delivering the stimulation pulses from the electrodes of the at least one stimulator to the at least one peripheral nerve of the patient for the purpose of reducing the sensations of chronic peripheral pain experienced by the patient;
wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve of the patient.
(emphasis added).

In contrast, neither Schulman nor Novak teach or suggest the claimed method for treating chronic pain which includes "at least one of chronic neuropathic pain, failed back surgery syndrome, arachnoiditis, occipital neuralgia, peripheral pelvic pain, cardiac pain and back pain."

These maladies are not even mentioned by Schulman or Novak. Nor would it have been obvious to one of skill in the art to take the teachings of Schulman and Novak and apply them to

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an entirely different group of patient conditions requiring stimulation at entirely different nerve locations. This subject matter simply is not taught or suggested by Schulman and Novak and clearly represents a patentable advance over those teachings.

As stated above, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). For at least this reason, the rejection of claim 15 and its dependent claims should be reconsidered and withdrawn.

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Conclusion:

The newly added claims are thought to be patentable over the prior art of record for at least the same reasons given above with respect to claim 1. Therefore, examination and allowance of the newly added claims is respectfully requested.

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper that have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: April 24, 2006


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I hereby certify that this correspondence is being transmitted to the Patent and Trademark Office facsimile number 571-273-8300 on April 24, 2006. Number of Pages: 21


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